K133476
FEB 12 2014

2.0 510(K) SUMMARY

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(a).

Submitter's name, address, telephone number, contact person, and date summary prepared

a.	Applicant:	Carl Zeiss Meditec AG Goeschwitzer Strasse 51-52 07745 Jena Germany
b.	Contact Person:	Sarah Harrington, MS, MBA Staff Regulatory Specialist Carl Zeiss Meditec, Inc. 5160 Hacienda Drive Dublin, CA 94568 sarah.harrington@zeiss.com Tel: (925) 560-5134 Fax: (925) 557-4259
c.	Date Submitted:	November 2013

Name of device, including trade name and classification name

a.	Trade/Proprietary Name:	SL 115 Classic Slit Lamp SL 120 Slit Lamp SL 130 Slit Lamp SL cam 5.0
b.	Common/Usual Name:	Slit Lamp Imaging Module for Documentation
c.	Classification Name:	AC-powered slit lamp biomicroscope Device, Storage, Images, Ophthalmic; Device, Communication, Images, Ophthalmic
d.	Product Code and Class:	HJO – Class II
e.	Classification Number:	886.1850

Predicate Device

The SL 115 Classic Slit Lamp, SL 120 Slit Lamp and the SL 130 Slit Lamp are similar in electro-optical design and function to the predicate devices, the ZEISS 20 SL Slit Lamp (K925641), the ZEISS 30 SL-L Slit Lamp (K862004) and the Righton Zoom Slit Lamp NS-2D with optional camera and video functions (K110129).

The optional digital imaging solution, the SL cam 5.0, presented in this 510(k) is similar in design and functionality to the optional camera and video offered by the Righton Zoom Slit Lamp NS-2D (K110129).

Device Description

The SL 115 Classic Slit Lamp, SL 120 Slit Lamp and the SL 130 Slit Lamp can perform a wide range of eye care applications. They are used for ophthalmic observation and image documentation of structural properties of the eye. The slit controls of the SL 115 Classic Slit Lamp, SL 120 Slit Lamp and the SL 130 Slit Lamp allow horizontal slit adjustment from either the right or left, vertical slit adjustments with a pinhole-type slit and allow viewing with the slit illuminator in the middle position. The instrument is primarily used by physicians, ophthalmologists, optometrists and eye care providers.

The optional SL cam 5.0 digital imaging solution provides an additional function to capture images and video sequences during an eye examination. It is not a data management system and it is not used for diagnosis. The SL cam 5.0 digital imaging solution does not control the slit lamps.

Indications for Use

The SL 115 Classic Slit Lamp, SL 120 Slit Lamp and SL 130 Slit Lamp are AC-powered slit lamp biomicroscopes intended for use in eye examination of the anterior eye segment, from the corneal epithelium to the posterior capsule. They are used to aid in the diagnosis of disease or trauma which affect the structural properties of the anterior eye segment.

The optional SL cam 5.0 is a digital imaging solution that allows the user to take images and video sequences for documentation purposes of the anterior eye segment during slit lamp examinations.

The SL 115 Classic Slit Lamp, SL 120 Slit Lamp and SL 130 Slit Lamp, combined with SL cam 5.0 are intended for use by physicians and ophthalmologist.

Comparison of Technological Characteristics

The SL 115 Classic Slit Lamp, SL 120 Slit Lamp and the SL 130 Slit Lamp and predicate devices, the ZEISS 20 SL Slit Lamp (K925641), the ZEISS 30 SL-L Slit Lamp (K862004), share similar functional features and operating characteristics.

The software based imaging solution, the SL cam 5.0, adds an additional feature to the SL 115 Classic Slit Lamp, SL 120 Slit Lamp and the SL 130 Slit Lamp for documenting image and video sequences. The Righton Zoom Slit Lamp NS-2D uses a similar digital imaging accessory (K110129).

Brief Summary of Nonclinical Tests and Results

The SL 115 Classic Slit Lamp, SL 120 Slit Lamp and the SL 130 Slit Lamp have demonstrated conformance to the following recognized performance standards:

- IEC 60601-1:2007, clauses 10.4, 10.5, 10.6, 10.7 with assessment of hazards caused by optical radiation of the slit lamp with the halogen lamp according to DIN EN ISO 10939:2007, clause 4.4 (cross references to ISO 15004-2:2007).
- IEC 60601-1:2005 CORR.1 (2006) +CORR.2 (2007).
- IEC 60601-1-2 (2007-12).

Software was tested according to a Carl Zeiss Meditec internal software development procedure that is in compliance to the IEC 62304:2006 – Medical device software – Software life cycle processes. The software was also tested following the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005.

Conclusion

Based on the test results and software verification and validation as well as the comparison to the predicate devices, the SL 115 Classic Slit Lamp, the SL 120 Slit Lamp and the SL 130 Slit Lamp used with the optional SL cam 5.0 digital solution are safe and effective with respect to their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 12, 2014

Carl Zeiss Meditec, Inc.
% Ms. Sarah Harrington, MS, MBA
Staff Regulatory Specialist
5160 Hacienda Drive
Dublin, CA 94568

Re: K133476
Trade/Device Names: SL 115 Classic Slit Lamp, SL 120 Slit Lamp, SL130 Slit Lamp, and SL cam 5.0
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-powered slit lamp biomicroscope
Regulatory Class: Class II
Product Code: HJO
Dated: November 13, 2013
Received: November 14, 2014

Dear Ms. Sarah Harrington:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: Registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological

Enclosure

1.0 INDICATIONS FOR USE – SL 115 CLASSIC, SL 120 AND SL 130 SLIT LAMP WITH SL CAM 5.0 DIGITAL IMAGING SYSTEM

510(k) Number (if known): K133476

Device Name(s): AC powered Slit Lamp Biomicroscope

Indications for Use:

The SL 115 Classic Slit Lamp, SL 120 Slit Lamp and SL 130 Slit Lamp are AC-powered slit lamp biomicroscopes intended for use in eye examination of the anterior eye segment, from the cornea epithelium to the posterior capsule. They are used to aid in the diagnosis of disease or trauma which affect the structural properties of the anterior eye segment.

The optional SL cam 5.0 is a digital imaging solution that allows the user to take images and video sequences for documentation purposes of the anterior eye segment during slit lamp examinations.

The SL 115 Classic Slit Lamp, SL 120 Slit Lamp and SL 130 Slit Lamp, combined with SL cam 5.0 are intended for use by physicians and ophthalmologists.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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